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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/634,320	08/09/2000	Mikhail I. Papisov	0838.1003-001	5525

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EXAMINER

ZARA, JANE J

ART UNIT PAPER NUMBER

1635

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/634,320	PAPISOV, MIKHAIL I.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-96 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

File

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DETAILED ACTION

This Office action is in response to the communication filed March 5, 2002, Paper No. 10.

Claims 1-96 are pending in the instant application.

Election/Restriction

Pursuant to 37 C.F.R. 1.142(a), whereby the distinctness and independence of the inventions of the instant application have become clear upon further consideration, an examiner's action on the merits of the communication filed by Applicant on March 5, 2002, insofar as they pertain to the elected invention, is hereby deferred until a new election has been made. (See MPEP 810.02 and 811)

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to methods of forming a drug-carrier complex, classified in class 435, subclass 6.
- II. Claims 14-54, drawn to drug-carrier compositions, classified in class 514, subclasses 1, 2, 44.
- III. Claims 55-78, drawn to methods of drug delivery, classified in class 424, subclasses 9.1 and 9.2.
- IV. Claims 79-80, drawn to methods of increasing aqueous solubility of a substance, classified in class 424, subclass 1.25.

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- V. Claims 81-84, drawn to targeted drug carrier complexes, classified in class 536, subclasses 1.11 and 23.1.
- VI. Claims 85-90, drawn to drug delivery systems comprising a matrix, classified in class 514, subclasses 1, 2, 44.
- VII. Claims 91-96, drawn to implants, classified in class 514, subclasses 1, 2, 44.

Applicants should note that Groups I-V are drawn to several inventions, and Applicant should select from one of the following inventions within Groups I-V:

Pick one drug selected from the group comprising a nucleic acid, a protein, a chemical such as an intercalator or a metal, a diagnostic such as a radioactive, paramagnetic, etc. **AND**

Pick one carrier selected from the group comprising a single stranded nucleotide, a double stranded nucleotide **AND**

Pick one polymer selected from the group consisting of a polysaccharide, a polyacetal or a polyether, **OR PICK ONE SPECIFIC COMBINATION** of two polymers, **OR** pick one oligomer selected from the group consisting of an oligosaccharide or an oligopeptide, **OR PICK ONE SPECIFIC COMBINATION** of two oligomers. The claims in each Group will be examined according to the limitations of the elected invention since some claims were found to be generic to patentably distinct groups.

Inventions I and III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

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different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I, III and IV comprise steps which are not required for or present in the methods of the other groups: methods of forming a drug-carrier complex (Group I), methods of drug delivery (Group III), and methods of increasing the aqueous solubility of a substance (Group IV). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The inventions are distinct, each from the other because of the following reasons: Inventions II and V and VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise compounds that are chemically, biologically, structurally, and functionally distinct from each other and thus one does not render the other obvious. The drug carrier compositions of Group I are structurally, chemically, biologically distinct from the targeted drug carriers of Group F, the drug delivery systems comprising a matrix of Group VI and the implants of Group VII. The compositions are not required to produce each other, and the invention of each group is capable of supporting a separate patent..

Inventions I, III, IV and II, V, VI, VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I, III, IV and Groups II, V, VI, VII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The drug-carrier complexes, targeted complexes, drug delivery systems comprising a matrix and implants are completely different and distinct from the operation, function and effects of the methods of Groups I, III and IV, which form complexes, solubilize substances and deliver drug complexes to organisms. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

May 20, 2002

TC 1600
JZ